

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )

Martine BARKATS *et al.* )

Serial No.: 08/776,786 )

Group Art Unit: 1632

Filed: May 1, 1997 )

Examiner: S. Priebe

For: ADENOVIRUS COMPRISING )  
A GENE CODING FOR )  
GLUTATHIONE PEROXIDASE )

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Assistant Commissioner for Patents  
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Sir:

**SUBMISSION OF INFORMATION UNDER 37 C.F.R. § 1.56**

To comply with its duty of candor and good faith under 37 C.F.R. § 1.56, and in the spirit of cooperating with the U.S. Patent and Trademark Office (hereafter, "the Office" or "PTO"), applicants and their assignee, Rhône-Poulenc Rorer S.A. ("RPR"), hereby voluntarily disclose to the Office information concerning the conduct of certain present and former employees of the assignee<sup>1/</sup> in prosecuting this patent application before the United States Patent and Trademark Office.

The conduct at issue concerns a practice in RPR's U.S. Patent Department, since terminated, wherein a former PTO patent examiner, who was at the time

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<sup>1/</sup> The employees actually worked for the assignee's U.S. affiliate, Rhône-Poulenc Rorer, Inc. In this submission, RPR refers to either RPR S.A. or RPR, Inc. RPR is presently doing business as Aventis Pharmaceuticals Products, Inc.

registered to practice before the Office, assisted in prosecuting matters that may have been within the scope of his 37 C.F.R. § 10.10(b) undertaking.

In light of the possibility that this conduct could be deemed to violate a PTO regulation, RPR hired Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. ("FHFGD"), to conduct a factual investigation. A report detailing the results of that investigation (entitled "Factual Report of an Independent Investigation Conducted on Behalf of Rhône-Poulenc Rorer, Inc.", hereafter, "Report"), and its supporting exhibits,<sup>2/</sup> have been submitted to the PTO in U.S. Reissue Application Serial No. 09/538,857, and are hereby incorporated by reference into this submission. A copy of the Report and its supporting exhibits were also filed with the Office of Enrollment and Discipline on October 4, 1999.

### INTRODUCTION

The relevant conduct relates to an RPR employee, R. Keith Baker, Ph.D. ("Baker"), as well as certain colleagues with whom Baker worked in RPR's Patent Department, who were involved in the prosecution of this patent application. Prior to working for RPR, Baker was employed as a patent examiner in the PTO for five years,

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<sup>2/</sup> The materials relied upon in this submission, or the relevant portions thereof, are present in the Report and supporting exhibits, which are designated throughout this paper as "Report, page \_\_\_\_" and "Exh. \_\_, page \_\_, P \_\_," where P1, for example, refers to paragraph 1.

until he resigned on October 28, 1994. Three days after his resignation from the PTO, Baker began his employment at RPR in Collegeville, Pennsylvania.

Under PTO regulations, a former patent examiner (who is registered to practice before the PTO) may not practice before the Office unless he or she signs a written undertaking not to prepare, prosecute or "assist in any manner in the preparation or prosecution" of any patent application disclosing subject matter in his area of responsibility at the PTO. 37 C.F.R. § 10.10(b). Patent examiners sign such an undertaking when they resign from the PTO. This undertaking applies to patent applications filed prior to and within two years from the date the examiner resigns from the Office.

Since he signed such an undertaking,<sup>3/</sup> Baker was barred from assisting in the prosecution of certain applications pending at the PTO prior to October 28, 1996, and is still barred from assisting in the prosecution of any applications that are the progeny of applications falling within his bar during those two years. Nonetheless, Baker assisted in the prosecution of RPR patent applications that may have fallen within the scope of his undertaking, even though he did not sign papers submitted to, or actually appear before, the Office with respect to such matters. See Report, Part II, Section H.

The current application was filed with the PTO as a U.S. national stage application on May 1, 1997—after October 28, 1996, the end of Baker's two-year bar

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<sup>3/</sup> See Supplemental Exhibit 28.

period under 37 C.F.R. § 10.10(b). This application, however, claimed the benefit of the filing date of an international application filed under the Patent Cooperation Treaty (PCT). The PCT application designating the United States was filed on July 26, 1995—within Baker's two-year bar period. It was not clear to Baker or applicants whether applications filed under these circumstances would fall within Baker's undertaking under 37 C.F.R. § 10.10(b). In a letter dated January 6, 1997, Baker asked the PTO whether he was permitted to prepare (*i.e.*, enter into the U.S. national stage) and prosecute PCT cases of this nature. See Exh. 5. Baker never received a response to this inquiry.

Thus, on April 14, 1999, soon after FHFGD was hired to conduct the factual investigation, Mr. Charles E. Van Horn wrote a letter to Mrs. Karen Bovard, Director of the Office of Enrollment and Discipline ("OED") at the time, requesting clarification of the PTO interpretation of 37 C.F.R. § 10.10(b)(2) as it applies to an international application filed under the Patent Cooperation Treaty. See Exh. 6. After Mr. Van Horn received a response from Mrs. Bovard on May 19, 1999 (Exh. 7), a follow-up letter was sent to Mrs. Bovard on May 27, 1999, requesting clarification with regard to the specific situation where an international application designating the U.S. is filed outside the U.S. within a former examiner's two-year bar period. See Exh. 8.

In a letter dated December 2, 1999, responding to Mr. Van Horn's letter of May 27, 1999, Mr. Harry I. Moatz, acting Director of OED, stated that a former examiner's undertaking under 37 C.F.R. § 10.10 applies to national stage applications claiming

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benefit from the filing date of an international application designating the United States, even if entry into the United States national stage, or the filing of a continuation application in the United States, does not occur until after the expiration of the two-year bar period. Subsequently, it was calculated that the filing date of this U.S. national phase of a PCT application fell within Baker's bar. On March 23, 2000, FHFGD conducted an interview with Baker, in the presence of his counsel, Eric W. Bloom, Esq., to review Baker's possible involvement in the prosecution of this U.S. national stage application.

Based on information gathered during FHFGD's investigation, applicants believe that the conduct at issue is not material under 37 C.F.R. § 1.56. Even so, applicants and their assignee are disclosing all information to the PTO that they are aware of pertaining to any possible violation of PTO regulations by its employees. Applicants are filing this submission: (1) expressly advising the PTO of the former examiner's activities, stating specifically where his involvement resides in this application; (2) advising the PTO what the actual facts are, while making it clear that further examination may be required if any PTO action was based on those activities; and (3) establishing patentability of the claimed subject matter based on the new, factually accurate, record. *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1572 (Fed. Cir. 1983).

Thus, applicants are voluntarily disclosing to the PTO that an RPR patent agent may have violated his PTO undertaking when he assisted "in any manner" in the

prosecution of this patent application, as well as all other relevant facts. This disclosure is in furtherance of complying with the duty of candor and good faith required by 37 C.F.R. § 1.56 and with any and all disclosure requirements imposed by 37 C.F.R. Part 10.

### **SPECIFIC CONDUCT AT ISSUE IN THIS APPLICATION**

#### **I. Baker's Assistance in the Preparation of Papers Submitted to the PTO**

In an interview with FHFGD attorneys on March 23, 2000, Baker confirmed that this patent application is one with subject matter that may have fallen within the scope of his undertaking under 37 C.F.R. § 10.10(b). *See also*, Report, page 8; Exh. 2. According to an internal "Patent/TM File Opening Paper" in RPR's internal prosecution file, this case was docketed to "RG2" (a docketing user ID code for Baker). *See* Report, pages 16-20.

Baker likely drafted a Preliminary Amendment, which was signed by Martin F. Savitzky, Esq. ("Savitzky"), and submitted with the U.S. national stage application to the Office on February 11, 1997. In addition, Baker stated that he may have helped prepare a Reply and Amendment, which was signed by Christine M. Hansen, Esq. ("Hansen"), and submitted on July 21, 1998.<sup>4/</sup>

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<sup>4/</sup> It is also possible that Baker had minimal involvement in the preparation of a Continued Prosecution Application (CPA) Request Transmittal paper, which was signed by Ross J. Oehler, Esq. ("Oehler") and submitted on February 26, 1999. Baker stated that he was not sure if he had any involvement in preparing this procedural paper.

## II. Additional Assistance by Baker

Baker stated that he wrote a handwritten note (signed "RG2") to Savitzky on September 2, 1997, regarding the election of claims in response to a restriction requirement. Baker also may have received an internal e-mail from a departmental secretary regarding a telephone call from an examiner on December 8, 1997, and the election of claims by Savitzky in response to a restriction requirement.<sup>5/</sup>

### REMARKS

Although Baker, as a former examiner, may have violated his undertaking under § 10.10(b) when he assisted "in any manner" in the prosecution of this case, applicants submit that this conduct, as well as the conduct of any other practitioner involved in the prosecution of this case, does not rise to the level of inequitable conduct before the Office under the standards set forth in Rule 56 and the relevant case law. In an

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Normally, Oehler would have made the decision to file a CPA, and a departmental secretary would have prepared the form. Interview of Baker, March 23, 2000.

<sup>5/</sup> In addition, Baker may have drafted two internal RPR correspondence memoranda dated February 2, 1998, and September 22, 1998, including commentary on Office Actions, which were signed and sent to colleagues at RPR-France by Savitzky and Oehler, respectively. Baker may have also received a copy of a correspondence dated January 30, 1997, sent by a colleague at RPR-France regarding a Declaration and Power of Attorney, as well as a correspondence addressed to him, which was sent by an attorney from FHFGD on January 31, 1997, regarding WIPO and PCT application papers that were accidentally sent to FHFGD. Baker may have also discussed issues with Raymond S. Parker, Esq., who corresponded by e-mail in October 1998 with colleagues at RPR-France regarding experimental data and U.S. prosecution.

abundance of caution, however, applicants submit that the effect of any misconduct is purged by their disclosure of it to the Office via this submission, as well as the Report and exhibits incorporated by reference.

**I. The Conduct at Issue Is Not Material**

"Applicants for patents are required to prosecute patent applications in the PTO with candor, good faith, and honesty." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). Moreover, applicants are required to disclose material information to the PTO. "[A]ffirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with the intent to deceive" constitutes inequitable conduct. *Id.*

An inequitable conduct analysis requires consideration of several issues before a final determination is reached:

1. The tribunal must determine whether the misrepresentation meets a threshold level of materiality;
2. It must also determine whether the evidence shows a threshold level of an intent to mislead the PTO;
3. Once the threshold levels of materiality and intent have been established, the tribunal weighs materiality and intent because the more material the misrepresentation, the less evidence of intent that will be required in order to find that inequitable conduct has occurred; and



4. In light of all of the circumstances, the tribunal must then determine whether the applicant's conduct is so culpable that the patent should be held unenforceable.

*See Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998).

The conduct described in this submission does not rise to the level of inequitable conduct because it does not meet the required threshold level of materiality.

Information regarding the relevant conduct would not be important to a reasonable examiner in deciding whether to grant a patent, and the applicants did not gain any unfair advantage in the examining process from Baker's involvement.

The applicants did not benefit from any undue influence on the examiner(s) responsible for this application stemming from any prior relationship with Baker. The investigation unequivocally shows that during the prosecution of this application Baker did not directly interact with the PTO or its employees. As noted above, he never signed a paper submitted to the Office. Also, during prosecution of this application, he never communicated directly with PTO personnel, either by telephone or in person. See Report, page 49. Baker could not improperly assert influence on the examiner(s) if there was no knowledge of his involvement with the case.

Applicants also submit that Baker may not have had an intent to deceive the Office regarding his involvement in the prosecution of this case since Baker was uncertain whether U.S. national stage applications of this nature would fall within his PTO bar. See Exh. 5. Even assuming that Baker had an intent to deceive the PTO by

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shielding his involvement in the prosecution of this application from the Office, however, his actions were not material.

**A. The Former Examiner's Conduct Lacks Materiality**

In 1992, the PTO revised Rule 56 to more clearly define the information that applicants are required to disclose to the PTO:

- (b) Under this section, information is **material to patentability** when it is not cumulative to information already of record or being made of record in the application, and,
  - (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
  - (2) It refutes, or is inconsistent with, a position the applicant takes in:
    - (i) Opposing an argument of unpatentability relied on by the Office, or
    - (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56 (1992) (emphasis added).

This is the administrative standard for materiality in effect during the period of time in which the conduct at issue took place. If information is not material to patentability under this standard, the PTO does not require an applicant to disclose it to the Office.<sup>6/</sup> 57 Fed. Reg. 2023 (1992). The conduct described in the Report and herein does not fall within this definition of information "material to patentability" that an applicant must disclose to satisfy the duty of candor.

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<sup>6/</sup> See 37 C.F.R. § 1.56(a) ("There is no duty to submit information which is not material to patentability of any existing claim.").

While the information that a former examiner may have assisted in prosecuting this application is not cumulative of information already of record, applicants prior failure to disclose this information to the PTO does not violate the duty to disclose information material to patentability. This information does not, either alone or in combination with other information, establish a *prima facie* case of unpatentability of any claim that was pending in this application. In addition, it does not refute, nor is it inconsistent with, any position taken by applicants in opposing an argument of unpatentability or asserting an argument for patentability. The mere fact that a former examiner may have been involved with this application does not, *per se*, fall within the definition of materiality provided by 37 C.F.R. § 1.56.

Under the definition of materiality set forth in the former Rule 56 as promulgated from 1977 to 1992, "[i]nformation is 'material' when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." Even under this definition of "materiality," however, Baker's actions relating to the prosecution of this patent application are not material.

Baker's involvement was simply not germane to patentability issues considered during examination. His involvement in this application did not change the merits of the arguments and amendments submitted in support of patentability. No confidential information was used in preparing the papers submitted to the PTO. See Report, page 49, n.44. The examiner(s) who received these papers responded to them based on the

amendments and/or merits of the arguments therein. Baker's involvement would not have been important to a reasonable examiner in deciding to grant a patent.

Consequently, Baker's conduct was not material under the standard of the former Rule 56.

Applicants recognize that while revised Rule 56 states that submitting all information within the definition of § 1.56(b) will satisfy the duty to disclose information material to patentability, this does not necessarily mean that the broader duty of candor and good faith under § 1.56(a) has been satisfied. 57 Fed. Reg. 2022 (1992); M.P.E.P. § 2001.04 ("The language of 37 CFR 1.56 (and 37 CFR 1.555) has been modified effective March 16, 1992 to emphasize that there is a duty of candor and good faith which is broader than the duty to disclose material information."). In its final rule making in 1992, the PTO stated that amended Rule 56 "does not attempt to define the spectrum of conduct that would lack the candor and good faith in dealing with the Office which is expected of individuals who are associated with the filing or prosecution of a patent application." 57 Fed. Reg. at 2023.

Even if Baker's actions violate his section 10.10(b) undertaking and the broad duty of candor and good faith imposed by Rule 56, his actions do not constitute inequitable conduct. To constitute inequitable conduct, there must be an affirmative misrepresentation or failure to disclose information that gives the applicant an unfair advantage in the examining process. If the conduct in question does not relate to patentability of the claims or does not provide an applicant with an unfair advantage in

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the examining process, it is not material, and thus not a basis for sustaining a finding of inequitable conduct.

For example, one unfair advantage in the examining process that an applicant might seek to obtain is the expedited prosecution of a patent application without conducting a thorough search of the prior art. As one basis for being placed at the head of the examining line, an applicant must make a sworn statement that a prior art search has been done. In *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994) the Court noted:

The whole point of the PTO requirement that a petition to make special include a sworn statement that the applicant has made a *careful and thorough search* is that, in return for an applicant being put at the head of the examination line, he must make an extra effort to *look for* and produce all relevant prior art, in other words, to assist an examiner who is being asked to expedite examination.

*Id.*

The Federal Circuit went on to hold that, as a matter of law, making "a false statement in a petition to make special is material if . . . it succeeds in prompting expedited consideration of the application." *Id.* Thus, a misrepresentation relevant to providing required assistance to the examination process, coupled with an intent to deceive, which procured an unfair advantage that the applicant was not entitled to, was found to be material, and an inequitable conduct defense was sustained.

The importance of a misrepresentation's capacity to bear on patentability or the examination process and to induce an examiner to act, thereby providing an unfair

advantage to the applicant, is also evident in *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir.), *cert. denied*, 111 S. Ct., 1548 (1997) (hereafter, "*Eli Lilly*"). In *Eli Lilly*, the trial court ruled that one of the patents in suit was unenforceable for inequitable conduct because the applicants used an uncertified plasmid to hasten their determination of rat insulin-encoding cDNA sequences, and misrepresented in their specification that they had used another, certified plasmid.<sup>7/</sup> 119 F.3d at 1569.

On appeal, *Eli Lilly* argued that the determination of inequitable conduct should be upheld, relying on the holding in *General Electro Music*. *Id.* at 1570. Specifically, *Eli Lilly* argued that as long as the misrepresentation was made to obtain a patent more quickly than otherwise, then it is sufficient to support a finding of inequitable conduct.<sup>8/</sup> *Id.* The Federal Circuit did not agree that *General Electro Music* supported *Eli Lilly's*

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<sup>7/</sup> In 1976, NIH issued safety guidelines that governed the conduct of all NIH-supported research in the area of recombinant DNA. These guidelines established controlled conditions for the conduct of experiments involving the production of recombinant DNA molecules and their insertion into organisms, e.g., by plasmids. The safety guidelines mandated that no plasmid could be considered to fall within an approved classification until it had been certified for use by the NIH Recombinant DNA Advisory Committee. *Regents of the University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225, 1248-49 (D.C. S.D. Ind. 1995).

<sup>8/</sup> The U.C. applicants in the *Eli Lilly* case could not have disclosed using the uncertified vector in their application, because this would have violated NIH guidelines governing recombinant DNA experiments. To file their application earlier, *Eli Lilly* argued, the inventors falsified the identity of the vector in their application. *Id.* at 1570.

argument. The court distinguished its holding in that case, based on the impact the asserted misrepresentation had on the examiner:

In General Electro Music, we concluded that "a false statement in a petition to make special is material if, as here, it succeeds in prompting expedited consideration of the patent." We so concluded because, by filing a petition to make special, the applicant "requested special treatment and induced reliance on its statement that a prior art search had been conducted." As explained above, UC's alleged mischaracterization of the pMB9 work as an actual example did not induce the examiner to act, or not to act, in reliance thereon. **UC got no advantage in the patent examining process.** Therefore, we conclude that the district court clearly erred in finding that the misidentification of the plasmid was material to patentability.

*Id.* at 1571; emphasis added.

As was the case in *Eli Lilly*, applicants here received no unfair advantage in the patent examining process. Importantly, there was no opportunity for Baker to exert an undue influence on PTO personnel because he was not directly involved in the prosecution and he was never identified to the PTO with respect to this application.<sup>9/</sup> In

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<sup>9/</sup> Because Baker was never identified and did not appear before the Office during prosecution of this case, the present situation is clearly distinguishable from the facts of *Kearney & Trecker v. Giddings & Lewis*, 452 F.2d 579 (7<sup>th</sup> Cir. 1971), *cert denied*, 173 U.S.P.Q. 385 (1972) (claims held unenforceable in a patent infringement suit because plaintiff's remedial action did not "cleanse its hands" when an examiner retired from PTO and then worked on reissue of two patents, one of which he had originally allowed). Specifically, in *Kearney & Trecker*, the former PTO examiner: (1) was involved with the prosecution of the patent while at the Office; (2) left the PTO to work for the plaintiff who owned that patent; (3) participated in the prosecution of a reissue application of the patent, as well as the reissue of an acquired prior art patent; and (4) spoke directly to the examiner, a previous subordinate at the PTO, during the reissue proceedings. Furthermore, plaintiff's remedial action to purge the prohibited conduct occurred only after the conduct was uncovered during pretrial discovery in an infringement suit brought by the plaintiff.

addition, the documents and recollections of all present and former staff in the RPR Patent Department interviewed by FHFGD support the conclusion that no confidential information obtained from the PTO was used in prosecuting this or any of the other applications at issue. The lack of any evidence of an unfair advantage to RPR obtained from Baker's involvement in this application further supports the conclusion that his conduct does not satisfy the threshold level of materiality.

A finding of inequitable conduct requires that threshold levels of both intent and materiality be established. *Cf. Allen Organ Co. v. Kimball International, Inc.*, 839 F.2d 1556, 1567-68 (Fed. Cir. 1988) ("[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct.") Thus, even if Baker had an intent to shield his participation in this application from the PTO, a *prima facie* case of inequitable conduct cannot be established because his conduct was not material under any definition in the relevant PTO regulations and case law.

**B. The Conduct of the Other Practitioners Lacks Intent and Materiality**

Baker's conduct is not the only conduct that applicants bring to the Office's attention. The conduct of other registered professionals also may be relevant.

As discussed above, Savitzky and Hansen may have each reviewed and signed a substantive paper prepared by Baker. See "Specific Conduct At Issue In This Application" on pages 6-7 of this paper. Facts uncovered during an independent investigation by FHFGD, however, indicate that these individuals never had a clear understanding of Baker's section 10.10(b) undertaking. See Report, page 43.



Furthermore, Savitzky and Hansen believed that reviewing and signing of papers prepared by Baker was acceptable conduct. *Id.*; Report, page 30 and Part II, Section G. In other words, they all thought that they were abiding by PTO regulations, including section 10.10(b).

"To be guilty of inequitable conduct, an applicant must have intended to deceive the PTO by failing to disclose material information." *Braun Inc. v. Dynamics Corp. of America*, 975 F.2d 815, 822 (Fed. Cir. 1992). "There must be not only a misrepresentation, but also actual knowledge of falsity . . . ." *Jaskiewicz v. Mossinghoff*, 822 F.2d 1053, 1058 (Fed. Cir. 1987). "[T]he involved conduct, viewed in light of all of the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988); *Jaskiewicz*, 822 F.2d at 1059 (holding that when determining whether a practitioner has violated his duty of candor under Rule 56, "[t]he PTO must look to all the facts and circumstances involving the questionable conduct before finding intentional misconduct"). Applicants submit that the individuals who may have reviewed and signed papers for Baker did not act with an intent to mislead the PTO.

Savitzky and Hansen never had a firm understanding of Baker's PTO bar, in terms of either the barred subject matter or the contours of the actual undertaking itself. In fact, Baker himself did not know whether U.S. national stage applications of this kind

would fall within his PTO bar. See Exh. 5. Moreover, Baker was the first, and only, former patent examiner hired by the assignee. Report, page 40. Although there was a general understanding that Baker was precluded from working on some applications, the details of that proscription were not known by other members of the RPR Patent Department. *Id.*, pages 30, 42-45. Savitzky and Hansen never reviewed Baker's letter from OED defining the scope of his undertaking. *Id.*, page 21; Exh. 21, page 2. They believed in good faith that the practice at RPR regarding Baker did not violate PTO regulations.

Savitzky believed that as long as Baker's involvement in the application within the scope of his undertaking was shielded from the PTO, thereby preventing any possibility of an undue influence working to RPR's advantage, they were conducting themselves appropriately under, and in compliance with, the rules governing conduct before the PTO. Exh. 17, page 77, line 2 - page 78, line 14.

Hansen was aware that others were signing papers for Baker—she thought it was a system that Savitzky put together—and she didn't question the system. Since other members of the department were also signing for her initially (*i.e.*, before she received her PTO registration number in 1997), she didn't think anything was out of the ordinary. Exh. 21, page 2, P2, P7.

Accordingly, applicants submit that by reviewing, adopting, and signing papers Baker drafted, Savitzky and Hansen were not acting with a deliberate intent to deceive

the PTO. Perhaps the most telling evidence in support of this conclusion is the fact that they signed the papers at all. If these members of the assignee's Patent Department signed papers drafted by Baker, knowing that by doing so they would be participating in a deception of the PTO, they arguably would have been exposing themselves to the prospect of being disciplined under 37 C.F.R. § 10.23(c)(2)(ii). Although one's own denial of intent to deceive "may not be sufficient to overcome circumstantial evidence of intent to deceive," *Lipman v. Lehman*, 1996 U.S. Dist. LEXIS 10479 (D.D.C. 1996), *aff'd sub nom, Lipman v. Dickinson*, 174 F.3d 1363 (Fed. Cir. 1999), the circumstantial evidence here does not indicate that any of the members of RPR's patent department who signed Baker's papers did so with the deliberate intent of deceiving the PTO.

Furthermore, if Baker's actions are not material (for the reasons set forth in the above section), then the conduct of the other members of the department is also not material. Before signing and submitting the papers to the PTO, Baker's drafts were reviewed, typically edited, and adopted by the signers. Report, Part II, Section H. No confidential information was used in preparing these papers. *Id.*, page 49, n.44. Thus, a reasonable examiner would have examined the papers as if they had been prepared by the signer. In fact, the PTO examiner(s) responsible for this application responded to these papers based on the amendments and/or merits of the arguments therein.

Since no confidential information was used during prosecution, and applicants received no unfair advantage in the patent examining process, the identity of the drafter

of these papers has no bearing on the merits of the arguments. Thus, applicants believe that the examiner(s) would not have decided anything differently regarding the patentability of the claims, regardless of whether Baker or anyone else in the RPR Patent Department drafted the papers. The fact that Baker drafted or helped draft papers signed by others in the RPR Patent Department, therefore, should not be found material to patentability or material under any definition in the PTO regulations. Accordingly, applicants submit that the conduct does not rise to the level of inequitable conduct. See *Eli Lilly*, 119 F.3d at 1570-71.

## II. APPLICANTS PURGE THE EFFECT OF THIS CONDUCT

As explained above, applicants aver that no inequitable conduct was committed. If the conduct disclosed herein were to rise to the level of inequitable conduct, however, the effect of that conduct may be purged. Therefore, in an abundance of caution, applicants hereby submit all relevant information in this paper, as well as the Report and corresponding exhibits, to affect a "cure" or "purge" of any possible inequitable conduct committed by RPR employees in the prosecution of this case.

The controlling precedent on purging inequitable conduct is *Rohm and Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556 (Fed. Cir. 1983). In *Rohm and Haas*, the Federal Circuit set out three requirements that an applicant must satisfy to cure misconduct before the PTO:

The **first** requirement to be met by an applicant, aware of misrepresentation in the prosecution of his application and desiring to overcome it, is that he expressly advise the PTO of its existence, stating specifically wherein it resides. The **second** requirement is that, if the misrepresentation is of one or more facts, the PTO be advised what the actual facts are, the applicant making it clear that further examination in light thereof may be required if any PTO action has been based on the misrepresentation. **[Third]**, on the basis of the new and factually accurate record, the applicant must establish patentability of the claimed subject matter.

*Rohm and Haas*, 722 F.2d at 1572 (emphasis added). Where an intentional material misrepresentation has been made, a complete cure must be demonstrated by "clear, unequivocal, and convincing evidence." *Id.*

To comply with their duty of candor and fair dealing with the Office, and in accordance with the Federal Circuit's mandate in *Rohm and Haas*, applicants hereby expressly inform the PTO of the following:

1. A former examiner has assisted in prosecuting this application and that assistance may constitute a violation of his § 10.10(b) undertaking. A detailed description of the relevant conduct, both in general and specifically as it applies to this application, is described in the attached Report and its supporting exhibits. Also, the facts that are relevant to this application appear in the section entitled "Specific Conduct at Issue in this Application" of this paper.

2. The section entitled "Specific Conduct at Issue in this Application" on pages 6-7 sets forth the actual facts, as developed by an independent investigation

performed at the assignee's request. This section discloses the most significant instances in which Baker assisted the prosecution of this case. Although no definition of "assisting in any manner" is provided in the regulations, applicants have broadly interpreted it for the purpose of this submission and the Report. Thus, out of caution, all known details of Baker's involvement in the prosecution of this case are presented in the Report and supporting exhibits, which are incorporated by reference.

Applicants are not aware of any PTO actions based on conduct described above. Nonetheless, they request further examination of this application based upon the factually accurate record.

3. Applicants submit that the factually accurate record does not impact on the patentability of the claimed subject matter. The instant facts are unlike a situation where material prior art was deliberately withheld from the PTO—prior art that might render the claims unpatentable. Neither is it like a situation, as in *Rohm & Haas*, where false data is submitted to the PTO with a deliberate intent to deceive.

As discussed above, Baker did not make use of confidential information, he could not have unduly influenced PTO employees because his actions were not known to the Office, and the amendments and arguments submitted to the PTO have already been evaluated on their merits. When viewed in the context of the factually accurate record, the merits of those arguments do not change. If the Office considered them

persuasive before, they should still be so. Thus, applicants submit that the disclosed conduct has no effect on the patentability of the claimed invention.

**SUMMARY**

Applicants believe that this submission satisfies their duties of candor and disclosure to the Office as those duties apply to the conduct described above. They respectfully request further examination of the application in light of this disclosure.

Please grant any extensions of time required to enter this paper and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

By: *Steven P. O'Connor*  
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Reg. No. 41,225

Dated: June 16, 2000

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